

## **REMARKS**

The Office Action dated December 9, 2004, has been carefully considered. Claims 1-22 are pending in the present application. Claims 1 and 12 have been amended to clarify the claim language. In particular, claims 1 and 12 have been amended herein to recite that the prefabricated tubular metal sidewall structure comprises “a plurality of filaments defining openings in the sidewall structure”. This amendment is fully supported by the originally filed specification and does not introduce new matter. For example, support can be found in the present specification at page 3, lines 32-33, and Figs. 1A and 2A.

Reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

### **I. CLAIM REJECTION UNDER 35 U.S.C. § 102(E)**

#### **Claims 1, 3, 6, 9-12, 17, And 20-22 Are Patentable Over U.S. Patent 5,449,382 To Dayton *et al.* (“Dayton”)**

Claims 1, 3, 6, 9-12, 17, and 20-22 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Dayton. This rejection is respectfully traversed.

The inventions of independent claims 1 and 12 are directed to an expandable stent for implantation in a patient comprising a prefabricated tubular metal sidewall structure having open ends and comprising a plurality of filaments defining openings in the sidewall structure. A coating is disposed on a surface of the prefabricated sidewall structure, wherein the coating comprises a hydrophobic biostable elastomeric material and a biologically active material. Claim 1 also recites that the coating continuously conforms to the structure in a manner that preserves the openings. Claim 12 also recites that the openings are substantially free of webbing. Claims 3, 6, and 9-11 depend from claim 1, and thus also include all the recitations of claim 1. Claims 17 and 20-22 depend from claim 12, and thus also include all the recitations of claim 12.

As explained in the present application, the tubular metal sidewall structure or body is formed of filaments. Specification, page 3, lines 32-33. In addition, “[t]he coating process enables the material to adherently conform to and cover the entire surface of the filaments of the open structure of the stent in a manner such that the open lattice nature of the structure of the braid or other pattern is preserved, in the coated device.” Specification, page 4, lines 18-21.

Dayton does not disclose or suggest an expandable stent comprising “a tubular metal sidewall structure having open ends and comprising a plurality of filaments defining openings in the sidewall structure” and a coating on such sidewall structure as required by the present claims. Dayton does not even disclose or suggest a sidewall structure comprising a plurality of filaments.

Thus, it is believed that claims 1 and 12 and the claims depending therefrom are patentable over Dayton. Withdrawal of this rejection and allowance of claims 1, 3, 6, 9-12, 17, and 20-22 are respectfully requested.

## **II. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A)**

### **A. Claims 2, 4, 7, 8, 13, 15, 18, and 19 Are Patentable Over Dayton In View Of U.S. Patent No. 5,464,650 To Berg *et al.* (“Berg”)**

Claims 2, 4, 7, 8, 13, 15, 18, and 19 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dayton in view of Berg. This rejection is respectfully traversed.

Claims 2, 4, 7 and 8 depend from claim 1 which was shown above to be patentable over Dayton. Claims 13, 15, 18, and 19 depend from claim 12 which was also shown to be patentable over Dayton. In particular, Dayton does not disclose or suggest a stent comprising a structure comprising a plurality of filaments defining openings in the sidewall structure and a coating on such structure.

Berg does not remedy the deficiencies of Dayton. Unlike the present invention, Berg does not describe or suggest a coated stent having openings therein, wherein the coating continuously conforms to the structure in a manner that preserves the openings or wherein the openings are substantially free of webbing as recited in the present claims. Berg is completely silent as to whether the openings in its stent contain a webbing of coating material. Furthermore, one of ordinary skill in the art would not be motivated to combine Berg with Dayton where Dayton does not even disclose or suggest a sidewall structure comprising a plurality of filaments defining openings in the sidewall structure.

Accordingly, it is believed that claims 2, 4, 7, 8, 13, 15, 18 and 19 are patentable over Dayton in view of Berg. Withdrawal of this rejection and allowance of claims 2, 4, 7, 8, 13, 15, 18 and 19 are respectfully requested.

**B. Claims 5 and 16 Are Patentable Over Dayton In View Of U.S. Patent No. 5,464,650 To Berg *et al.* (“Berg”)**

Claims 5 and 16 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dayton in view of Berg. This rejection is respectfully traversed.

Dependent claims 5 and 16 recite that the “coating is about 75 to about 200  $\mu\text{m}$  in thickness.” Claim 5 depends from claim 1 and claim 16 depends from claim 12. Claims 1 and 12 were shown above to be patentable over Dayton in view of Berg. For the reasons discussed above, it is believed that claims 5 and 16 are also patentable over Dayton in view of Berg. In addition, as acknowledged by the Examiner, neither Dayton nor Berg disclose a particular thickness of the coating. One skilled in the art would not find motivation to combine the teachings of Dayton and Berg to obtain the present invention where neither reference discloses a particular thickness of the coating and Dayton does not even disclose or suggest a sidewall structure comprising a plurality of filaments defining a plurality of openings.

Accordingly, it is believed that claims 5 and 16 are patentable. Withdrawal of this rejection and allowance of claims 5 and 16 are respectfully requested.

**C. Claim 14 Is Patentable Over Dayton In View Of EP 0565542 To Burton *et al.* (“Burton”)**

Claim 14 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dayton in view of Burton.

Claim 14 depends from claim 1 which was shown above to be patentable over Dayton. Burton does not remedy the deficiencies of Dayton.

Like Dayton, Burton does not disclose or suggest a tubular metal sidewall structure comprising a plurality of filaments defining openings in the sidewall structure. Burton does not even disclose or suggest a tubular *metal* sidewall structure. Burton only discloses a tubular member that is “fabricated from a thermoplastic material.” Column 3, lines 16-17.

Burton also discloses that the “stent of the present invention comprises a non-braided thermoplastic web or mesh.” Column 3, lines 24-25. Burton further discloses that the “material from which the stent 10 is formed may be a thermoplastic having a high modulus of elasticity such that when it is subjected to inwardly directed radial forces uniformly applied over its surface, it will collapse to a lesser diameter.” Column 4, lines 30-34. By disclosing a stent made from a thermoplastic having a high modulus of elasticity, Burton teaches away from stent comprising a metal sidewall structure.

Burton also does not disclose or suggest "a coating on a surface of the sidewall structure, said coating comprising a hydrophobic biostable elastomeric material and a biologically active material, wherein the openings are substantially free of webbing" as recited in claim 12. Burton does not even disclose or suggest the use of any coating on a stent.

One of ordinary skill in the art would not find motivation in the disclosures of Dayton or Burton to combine the teachings of these references to obtain the present invention where both Dayton and Burton do not disclose a metal sidewall structure comprising a plurality of filaments. One of ordinary skill in the art would also not find motivation in the disclosures of Dayton or Burton to combine the teachings of these references to obtain the present invention where Burton does not even disclose a metal sidewall structure or a coating disposed on a surface of such structure.

Accordingly, it is believed that claim 14, which depends from claim 12, is patentable over Dayton in view of Burton. Withdrawal of this rejection and allowance of claim 14 are respectfully requested.

### **III. CONCLUSION**

As all rejections are believed to be overcome, all claims are believed to be in condition for allowance. Reconsideration and allowance of the present application are respectfully requested. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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